



Strep A Test

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the QuickVue In-Line Strep A Test?

The suggested CPT code is 87880QW.* For the current Medicare National Limit amount** [click here](#).

What is the CLIA complexity of this kit?

The test is CLIA waived.

How often should external controls be run on the kit?

Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits – provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.

What is the shelf life and kit storage of the QuickVue In-Line Strep A kit?

The shelf life is 24 months from date of manufacture. The kit should be stored at room temperature (59°F to 86°F, 15°C to 30°C)

Can transport media be used with this kit?

No, transport media cannot be used with the QuickVue In-Line Strep A kit.

Can I use other swabs with this kit?

The sterile rayon-tipped swabs supplied with this kit must be the only swabs used for specimen collection. The QuickVue In-Line Strep A Test swabs are specifically engineered with larger tips to fit snugly into the testing device well. Other swabs (including proficiency samples) will not perform consistently with this test, and discrepant results can occur. To order additional swabs, use Quidel Cat. #00347.

Why is the Proficiency Testing procedure for the QuickVue In-Line Strep A Test different from the regular procedure?

The sample swab provided for Proficiency Surveys has a smaller tip that will not be compatible with the QuickVue In-Line Strep A Test device; results will not be consistent. Please refer to the QuickVue In-Line Package Insert Proficiency Testing Survey Procedure section for instructions on proficiency testing.

Do I have to do Proficiency Testing?

Usually, facilities that perform moderately complex tests have been mandated to perform Proficiency Testing. Waived tests do not require Proficiency Testing unless the governing agencies, or your internal quality control requirements, have their specific guidelines that supersede federal guidelines.

Can the test be read after the designated read time?

The QuickVue In-Line Strep A Test should be read at 5 minutes. Some positive results may appear sooner.

What is the amount of liquid from the dropper in the Proficiency Test kit provided in the QuickVue In-Line Strep A kit?

Approximately 350 µL.

Is it okay if I accidentally touch the inside cheeks or tongue with the collection swab?

No, this may cause an interference with our test chemistry. The sample should be re-collected.

Is the Positive Control Swab infectious?

No. The swab has been inoculated with heat-inactivated Group A *Streptococcal* antigen and is not infectious.

Do I have to do a culture if the test is negative?

Quidel recommends additional follow-up testing using the culture method if the QuickVue In-Line Strep A test result is negative.

The FDA states, "Since no rapid test has been cleared, approved, or waived through the regulatory process as a stand-alone test in the face of locally suppurative disease, lack of a backup method for a negative rapid GAS test result constitutes off label use." Below is the link for reference:

<https://wayback.archive-it.org/7993/20170112085448/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109407.htm>

How long after breaking the QuickVue In-Line Strep A Test Extraction Reagent Delivery Device is it still good?

The ERDD should not be activated (by crushing) until the test is ready to be performed. It should be used immediately.

Why is the QuickVue In-Line Strep A Test sample not flowing?

The swab may be plugging the aperture from the chamber to the test strip. If you still observe no flow after 1 minute, take out the swab and reinsert it into the chamber. Do not re-set timer.

How long after antibiotic treatment will the patient show positive?

This test detects the presence of the antigen. Depending on the individual, and their compliance with antibiotic therapy, the antigen may remain present for 2-3 weeks after the initiation of antibiotic treatment, even though the patient's signs and symptoms of pharyngitis are gone.

**Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.* Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

**For state by state fee schedule go to www.cms.gov. "QW" modifier is added to report use of CLIA-Waived test system(s) for Medicare/Medicaid claims.